Attorney Docket No.: Inventors:

PENN-0789 Siegel et al. 10/046,504

Serial No.: Filing Date:

October 19, 2001

CENTRAL FAX CENTER
AUG 0 3 2006

RECEIVED

Page 3

This listing of the claims will replace all prior versions and listings of claims in the application:

## Listing of the claims:

Claim 1: (currently amended) A surgically implantable drug delivery system consisting essentially of biodegradable polymer or copolymer selected from the group consisting of polylactide and lactide-co-glycolide copolymer and 20 to 40% haloperidol fabricated into an individual, surgically implantable implant via solvent casting and compression molding at a temperature and pressure which allows the haloperidol-polymer material to flow into a mold for the individual, surgically implantable implant which is surgically implanted underneath the skin of a patient, delivers steady state concentrations of haloperidol to the patient for 5 months or more and is removable from the patient in the event the patient exhibits unwanted side effects following implantation.

Claim 2 (canceled)

Claim 3 (currently amended): The surgically implantable drug delivery system of claim 1 comprising wherein the biodegradable polymer or copolymer is 50 to 100% polylactide and 0 to 50% polyglycolide.

Attorney Docket No.: Inventors:

PENN-0789 Siegel et al.

Serial No.:

10/046,504 October 19, 2001

Filing Date: Page 4

Claim 4: (currently amended) A method of producing an individual, surgically implantable implant which is surgically implanted underneath the skin of a patient for delivery of steady state concentrations of haloperidol to the patient for five months or more comprising:

- (a) dissolving haloperidol and a biodegradable polymer selected from the group consisting of polylactide and lactide-co-glycolide copolymer in acetone;
- (b) solvent casting the haloperidol and biodegradable polymer solution to produce a completely dry haloperidol-polymer material; and
- (c) molding under compression the dry haloperidol-polymer material at a temperature and pressure which allows the haloperidol-polymer material to flow into a mold for the individual, surgically implantable implant which is surgically implanted underneath the skin of a patient, delivers steady state concentrations of haloperidol to the patient for 5 months or more, and is removable following implantation into a patient in the event the patient exhibits unwanted side effects following implantation.

Claim 5 (canceled)

Attorney Docket No.:

PENN-0789 Siegel et al. 10/046,504

Serial No.: Filing Date:

Inventors:

October 19, 2001

Page 5

Claim 6 (original): The method of claim 4 wherein the biodegradable polymer comprises 50 to 100% polylactide and 0 to 50% polyglycolide.

Claim 7: (original) A method for treating patients with psychotic conditions and diseases comprising surgically implanting into a patient suffering from a psychotic condition or disease the surgically implantable drug delivery system of claim 1.

Claim 8: (original) The method of claim 7 wherein the surgically implantable drug delivery system is implanted under the skin of a patient between the muscle and dermis.

Claim 9: (original) The method of claim 7 wherein the patient is suffering from schizophrenia.

Claim 10: (original) The method of claim 7 further comprising administering to the patient an antipsychotic drug orally.

M. Endo, et al.

U.S.S.N.: 09/787,157

Page 4 of 4

b. \_\_\_\_ no item of information contained in the IDS was cited in a communication from a foreign Patent Office in a counterpart foreign application or, to the best of my knowledge after making reasonable inquiry, was known to any individual designated in 37 C.F.R. § 1.56(c) more than three months prior to the filing of this

Some of the items of information were cited in a communication from a foreign Patent Office. As to this information, the undersigned certifies that each item of information contained in the IDS was cited in a communication from a foreign Patent Office in a counterpart foreign application not more than three months prior to the filing of this IDS. As to the remaining information, the undersigned hereby certifies that no item of this remaining information contained in the IDS was cited in a communication from a foreign Patent Office in a counterpart foreign application or, to the best of my knowledge after making reasonable inquiry, was known to any individual designated in 37 C.F.R. § 1.56(c) more than three months prior to the filing of this statement.

## VII. FEE PAYMENT (check one)

statement.

Enclosed please find a check in the amount of \$240.00 for the above-indicated fee.

Please charge Deposit Account No. 04-1105 in the amount of \$240.00 for the above-indicated fee.

X No fee is required.

If the Examiner has any questions concerning the IDS, he/she is requested to contact the undersigned. If it is determined that the IDS has been filed under the wrong rule, the PTO is requested to consider the IDS under the proper rule, with a petition if necessary, and charge the appropriate fee to Deposit Account No. 04-1105.

Lisa Swiszcz Hazzard (Reg. 44,368)

EDWARDS & ANGELL, LLP

P.O. Box 55874 Boston, MA 02205

617-439-4444

Customer No.: 21874

438427

**FORM PTO-1449** ATTY DOCKET NO. SERIAL NO. INFORMATION DISCLOSURE STATEMENT 55710 (70968) 09/787,157 APPLICANT(S) M. Endo, et al. 3/14/01 FILING DATE **GROUP NO.** 1771 UNITED STATES PATENT DOCUMENTS FILING DATE EXAM. DOCUMENT INITIAL NUMBER DATE NAME CLASS **SUBCLASS** IF APPROPRIATE AA 4,410,582 10/18/83 Tsunashima, et al. 428 212 AB 5,773,142 06/30/98 Murschall, et al. 428 349 FOREIGN PATENT DOCUMENTS DOCUMENT TRANSLATION NUMBER DATE **COUNTRY** CLASS SUBCLASS YES/NO OTHER DOCUMENTS (INCLUDING AUTHOR, TITLE, DATE, PERTINENT PAGES, ETC.)

DATE:

438424

**EXAMINER:**